

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
)	MDL No. 13-2419
)	Dkt. No 1:13-md-2419 (RWZ)
_____)	
THIS DOCUMENT RELATES TO:)	
)	
All Cases Against the Saint Thomas)	
Entities)	
)	
_____)	

**SAINT THOMAS ENTITIES' MEMORANDUM IN SUPPORT OF THEIR GLOBAL
MOTION FOR PARTIAL SUMMARY JUDGMENT ON CLAIMS FOR ACTUAL
AGENCY AND DIRECT LIABILITY**

Pursuant to Federal Rule of Civil Procedure 56, the Saint Thomas Entities¹ file this Memorandum in Support of their Global Motion for Partial Summary Judgment on Claims for Actual Agency and Direct Liability as to the MDL Plaintiffs bringing claims against them ("Tennessee Plaintiffs"), and in support, show the Court as follows:

INTRODUCTION

The Saint Thomas Entities have been made parties to the cases against them in this multidistrict litigation because Saint Thomas Network is a 50% investor in Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC")—an ambulatory surgery center that administered contaminated methylprednisolone acetate ("MPA"). Neither the Saint Thomas Entities nor STOPNC had any role in causing the contamination. Nor did they have any knowledge of any contamination by the New England Compounding Center ("NECC").

¹ Saint Thomas West Hospital, formerly known as St. Thomas Hospital ("Hospital"), Saint Thomas Network ("Network"), and Saint Thomas Health ("Health") (collectively, the "Saint Thomas Entities").

Plaintiffs' first assertion of liability against the Saint Thomas Entities is purely vicarious—based on their relationship (or alleged relationship) with the STOPNC Defendants.² Hospital and Health have no ownership interest in STOPNC. The individual defendants are alleged to be employees of STOPNC,³ and none of the Saint Thomas Entities employed, supervised, directed, or controlled any of the STOPNC Defendants accused of wrongdoing. The Saint Thomas Entities did not have any right of control over the operations of STOPNC or the Howell Allen Clinic employees who ran it. Nor is there anything in the record to suggest that these Defendants actually exercised any control over STOPNC. After deposing at length numerous witnesses from both sets of Defendants, there is absolutely nothing to suggest that there were *any* communications between the Saint Thomas Entities and the STOPNC Defendants about procuring pharmaceutical products from compounding pharmacies generally or NECC in particular. The Tennessee Plaintiffs' actual agency claims against the Saint Thomas Entities should be summarily adjudicated, as the undisputed facts demonstrate that there is no basis for imposing vicarious liability against any of the Saint Thomas Entities under an actual agency theory.⁴

Some of the Tennessee Plaintiffs have also made vague allegations of “direct liability” against the Saint Thomas Entities premised on the notion that these Defendants negligently “operated” STOPNC in such a way that “facilitated” its procurement of contaminated steroids, but

² The “STOPNC Defendants” consist of STOPNC, Howell Allen Clinic, P.C. (“Howell Allen Clinic”), John Culclasure, M.D. (“Dr. Culclasure”), Debra Schamberg, RN, CNOR (“Nurse Schamberg”), and Vaughan Allen, M.D.

³ See Original Master Complaint ¶¶ 346-48. Citations in this Memorandum are explained in the *Saint Thomas Entities' Statement of Undisputed, Material Facts in Support of their Global Motion for Partial Summary Judgment on Claims for Actual Agency and Direct Liability* (“STE SMF”), which is filed contemporaneously.

⁴ The Tennessee Plaintiffs have also alleged apparent or ostensible agency theories for holding some or all of the Saint Thomas Entities vicariously liable for the actions of the STOPNC Defendants under Tennessee law. These claims implicate the particular facts and experiences of the individual Plaintiffs and therefore are not suitable for a global summary judgment. The Saint Thomas Entities reserve their rights to seek summary judgment on those claims during the case-specific development phase of the litigation.

they have not stated a viable claim under Tennessee law. The Saint Thomas Entities had absolutely no relationship to the Tennessee Plaintiffs at the time they sought treatment at STOPNC, and there is no basis under Tennessee law for imposing a duty on the Saint Thomas Entities under the circumstances. Even if the Tennessee Plaintiffs could articulate a legally cognizable duty, there is no evidence that the Saint Thomas Entities had a right of control over the operations of STOPNC, exercised actual control over the company, or otherwise had any involvement in the procurement of NECC-compounded MPA. This claim fails as a matter of law. The Court should therefore grant summary judgment on both the actual agency and direct liability claims.

SUMMARY OF CLAIMS

The Tennessee Plaintiffs' claims are among many in this MDL arising out of injections of steroids compounded by NECC that are claimed to have caused injuries to the patients who received them. The Tennessee Plaintiffs include patients who received epidural injections of MPA at STOPNC and were later diagnosed with fungal meningitis and their respective family members, as well as other patients who received epidural injections of MPA at STOPNC and were later diagnosed with less severe injuries or no injury at all. The MDL Plaintiffs claim that NECC compounded the MPA in unsanitary conditions, leading to contamination with microbial contaminants. *E.g.*, Second Amended Master Complaint ("Live Master Complaint") (Docket #1719) at ¶¶ 1-3.

Relevant to this motion, the Tennessee Plaintiffs allege only derivative liability against the Saint Thomas Entities. In varying forms and degrees, they assert that STOPNC is the "actual, ostensible, and apparent agent" of Hospital because (i) they share a "common name;" (ii) STOPNC is located in the Saint Thomas Medical Plaza East medical office building on the hospital campus; and (iii) STOPNC "instructed many patients to report to the St. Thomas Hospital emergency room for evaluation and treatment" during the fungal meningitis outbreak.

For context, the Saint Thomas Entities rely on the Master Complaint in Master Docket No. 1:13-md-2419-RWZ (Docket #545) (“Original Master Complaint”), and the Live Master Complaint (Docket #1719). The Original Master Complaint was incorporated by reference in the Live Master Complaint. *See* Live Master Complaint at 1 n.1. The allegations relating to the Saint Thomas Entities, however, are contained in the short-form complaints filed in individual cases. The Saint Thomas Entities will cite to six short-form complaints filed by the various Plaintiffs as representative specimens, all of whom have been designated as bellwether candidate plaintiffs:

- *Adam C. Ziegler, et al. v. Unifirst Corp., et al.*, No. 1:13-cv-12588-RWZ, filed by Lief Cabraser Heimann & Bernstein, LLP (“Ziegler Compl.”);
- *Fredia Berry, et al. v. Unifirst Corp., et al.*, 1:13-cv-12838-RWZ, filed by Branstetter, Stranch & Jennings PLLC (“Berry Compl.”);⁵
- *Reba M. Skelton, et al. v. Unifirst Corp. et al.*, No. 1:13-cv-12575-RWZ, filed by Kinnard, Clayton & Beveridge (“Skelton Compl.”);
- *Basil J. McElwee, et al. v. Ameridose LLC, et al.*, No. 1:13-cv-12625-RWZ, filed by Leader, Bulso & Nolan, PLC (“McElwee Compl.”); and
- *Denis Brock, et al. v. Unifirst Corp., et al.*, No. 1:13-cv-12731-RWZ, filed by Galligan & Newman (“Brock Compl.”)

In general, the Tennessee Plaintiffs assert that Network is an “owner and/or member” of STOPNC, which is a limited liability company, and that Network and Health “acted in concert” with Defendant Howell Allen Clinic “to operate jointly” STOPNC. Berry Compl. ¶ 27; Brock Compl. ¶ 5. The Tennessee Plaintiffs make similarly vague allegations about “Saint Thomas” being vicariously liable for STOPNC based on the shared name; proximity; assertions that Network purportedly operates STOPNC; STOPNC’s referral of suspected meningitis patients to St. Thomas Hospital for evaluation and treatment; and the allegation that “Saint Thomas” handles STOPNC’s contracting and finances. *E.g.*, Berry Compl. at ¶¶ 23(ii); 27(vii); Brock Compl. ¶ 5.

Finally, some Plaintiffs have alleged that both Health (Network’s owner) and Network were negligent in operating STOPNC “in a manner which facilitated the procurement of injectable

⁵ The PSC designated, and later struck, the *Berry* case. It is included to provide specimen pleadings from the plaintiffs’ attorneys’ groups representing a majority of the Tennessee Plaintiffs.

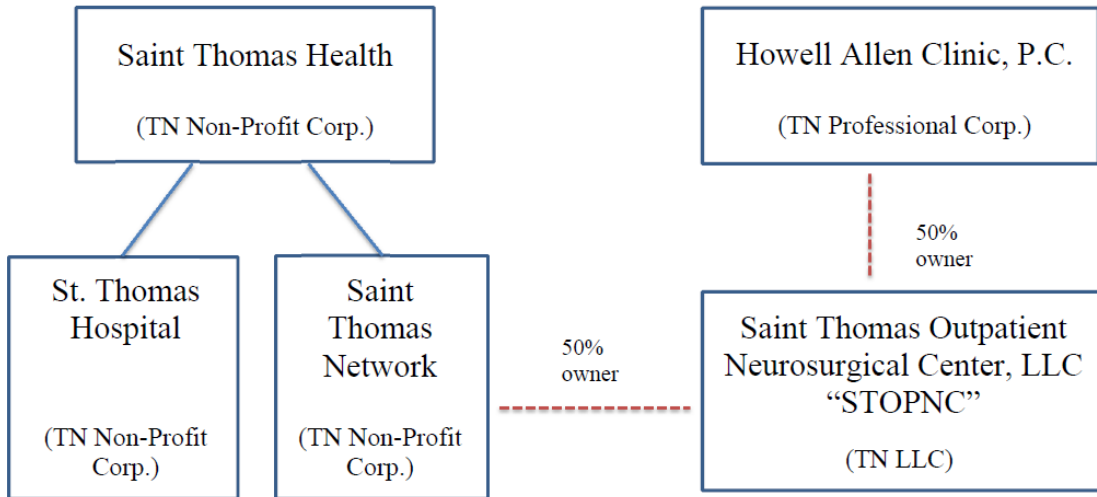
steroids from NECC . . . without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds.” *E.g.*, Berry Compl. ¶ 27(iv)(a).

Based on these general allegations, the Tennessee Plaintiffs allege a variety of claims, including strict products liability and medical negligence,⁶ against the STOPNC Defendants and the Saint Thomas Entities.

FACTUAL BACKGROUND

There is no allegation that any of the Saint Thomas Entities injected any of the Tennessee Plaintiffs with any medication from NECC. Nor is there any evidence (or assertion) that the Saint Thomas Entities ordered, procured or otherwise provided the contaminated steroids to STOPNC. Instead, all claims of liability against these Defendants derive from the alleged acts or omissions of the STOPNC Defendants. Howell Allen Clinic has at all relevant times employed the persons who decided to purchase medicine from NECC, namely Dr. Culclasure (STOPNC’s Medical Director) and Nurse Schamberg (STOPNC’s Facilities Director). STE SMF ¶ 1. These individuals reported to Howell Allen Clinic’s President and Chief Administrative Officer, respectively. *Id.* Dr. Culclasure and Nurse Schamberg were employees of Howell Allen Clinic—not any of the Saint Thomas Entities. *Id.* The Tennessee Plaintiffs do not identify any STOPNC actors who were employees of the Saint Thomas Entities. Consequently, the Tennessee Plaintiffs’ claims against the Saint Thomas Entities are based on nothing more than the corporate relationship between the Saint Thomas Entities and STOPNC. That relationship is depicted as follows:

⁶ Plaintiffs also asserted claims for civil conspiracy, battery, failure to warn (lack of informed consent), and violations of the Tennessee Consumer Protection Act. The Court dismissed the Plaintiffs’ civil conspiracy and battery claims for failure to state a claim, found that Plaintiffs’ informed consent claims were subsumed within the Tennessee Healthcare Liability Act, and dismissed the Tennessee Consumer Protection Act claims except to the extent the claims sought recovery “of monies used to purchase MPA.” *See* Memorandum of Decision (Aug. 29, 2014) (Docket #1360) at 63.



E.g., STE SMF ¶ 2-5.

In 2012, Health wholly owned five hospitals and a number of physician practices and rehabilitation facilities. STE SMF ¶ 2. Network, a wholly owned subsidiary of Health, had an ownership interest in a number of joint ventures, including STOPNC. *Id.* Health is a non-profit corporation organized under the laws of Tennessee. STE SMF ¶ 3. Network and Hospital are also non-profit corporations organized under Tennessee law. STE SMF ¶ 4. Network is essentially a holding company for joint-venture investments. *Id.*

STOPNC is a Tennessee limited-liability company owned 50% by Network and 50% by Howell Allen Clinic, a professional association of physicians. STE SMF ¶ 5. STOPNC is a joint-venture investment of Network. *Id.*

Under the agreement that defines their rights as owners, Howell Allen Clinic and Network each have the right to appoint two members of the Board of Governors of STOPNC. STE SMF ¶ 8. There is no allegation that Network, as owner, made negligent appointments to the STOPNC board. To the contrary, it is undisputed that Network's appointments were all highly regarded professionals with significant experience in the healthcare setting. *Id.* In other words, Network

appointed responsible, accomplished persons—top healthcare executives—to serve on the STOPNC board. These individuals had a fiduciary duty, recognized under every state’s law, to STOPNC. The Tennessee Plaintiffs have not alleged that these individuals in any way breached their fiduciary duties to STOPNC.

Pursuant to the Operating Agreement and their fiduciary duties as board members, STOPNC’s board appointed managers to run the business. STE SMF ¶ 9. It approved a services agreement with Howell Allen Clinic to provide the STOPNC employees and the Medical Director. STE SMF ¶¶9-10. The STOPNC board members understood their role, as defined under the Operating Agreement, as being “an oversight of the . . . financial affairs of STOPNC,” while “the business and the operations of the STOPNC were under [the] management agreement . . .” *Id.*

At the time of the meningitis outbreak in 2012, STOPNC’s Medical Director was Dr. Culclasure, and its Facilities Director was Nurse Schamberg. STE SMF ¶ 11. As Facilities Director, Nurse Schamberg oversees the day-to-day activities of STOPNC—“the staff and the running of the facility, anything that’s a part of the clinical side.” *Id.* As noted, both Dr. Culclasure and Nurse Schamberg were employees of Howell Allen Clinic who reported directly to Howell Allen Clinic executives. STE SMF ¶ 1. There is no allegation by any Plaintiff that the board acted inappropriately in selecting Howell Allen Clinic to manage the day-to-day affairs of STOPNC.

STOPNC is located on what is known as the St. Thomas Hospital campus. STE SMF ¶ 12. The medical office building in which STOPNC is located is owned by HRT, a real estate company that is not affiliated in any way with the Saint Thomas Entities. *Id.* Howell Allen Clinic (or its predecessor) is the tenant on the STOPNC lease. *Id.* Howell Allen Clinic also handles the billing for STOPNC and collects the money for patient procedures performed by STOPNC, including the epidural steroid injections (“ESIs”) that contained the NECC-compounded MPA. *Id.*

All of STOPNC's patients are referred by Howell Allen Clinic doctors. STE SMF ¶ 13. And if the steroid injections provided by STOPNC are not successful in resolving the patient's pain, then these patients may be referred back to the Howell Allen Clinic neurosurgeons. *Id.*

The responsibility for purchasing medications for STOPNC patients resided solely with Nurse Schamberg in consultation with Dr. Culclasure. STE SMF ¶ 14. At no point did Nurse Schamberg or Dr. Culclasure seek the advice of STOPNC's board or any board member regarding the decision to purchase medicine from NECC. STE SMF ¶¶ 15, 17. In fact, none of the Saint Thomas Entities had any involvement with the decision of Dr. Culclasure and Nurse Schamberg to purchase MPA from NECC. STE SMF ¶¶ 15, 17, 18. While the Hospital has its own pharmacy, it was not responsible for purchasing medications for STOPNC and has never supplied pharmaceuticals, medical supplies, or procurement services to STOPNC. STE SMF ¶ 15. The Hospital is a completely separate entity, *id.*, and there is no allegation that corporate formalities were not regarded or that any basis exists to disregard the corporate form. None of the Saint Thomas Entities had any involvement whatsoever in overseeing STOPNC's pharmaceutical practices, including setting policies as to what medications STOPNC would procure and provide to its patients. STE SMF ¶¶ 15, 17, 18. Dr. Culclasure testified that he never consulted with any pharmacist when making the decision to start purchasing MPA from NECC. STE SMF ¶ 17. He stated that he did not even know who Hospital's pharmacy director was. *Id.* According to STOPNC's medication errors policy, medication use was overseen by Nurse Schamberg and reported to STOPNC's Medical Executive Committee; none of the members of that committee were employed by any of the Saint Thomas Entities. STE SMF ¶ 16.

The Director of Pharmacy at Hospital at the time, Marty Kelvas, testified that he never consulted with STOPNC about compounding pharmacies in general or NECC in particular and was unaware of anyone in his department having any such consultation with STOPNC. STE SMF

¶ 18. Mr. Kelvas further testified that there was a “line [] drawn in the sand” between the for-profit ventures (including STOPNC) and the not-for-profit hospitals (including Hospital): “Our contracts were basically for the nonprofit side of the business. As far as any for-profit ventures, that’s a whole different class of trade. We had nothing to do with them.” *Id.* The decision by Nurse Schamberg and Dr. Culclasure to purchase NECC-compounded MPA was never brought to the attention of the STOPNC board before the meningitis outbreak. *Id.* In fact, there is no evidence that any of the STOPNC board members appointed by Network—or any other employee of the Saint Thomas Entities—was aware that STOPNC was purchasing products from a compounding pharmacy, including NECC. STE SMF ¶¶ 15, 17, 18.

Other than Network’s right to appoint individuals to serve on the Board of Governors (who then have a fiduciary duty to act in the best interests of STOPNC), the only interactions between the Saint Thomas Entities and STOPNC were defined by limited written fee agreements for specific support services. For example, Health has a single services agreement with STOPNC through which it provided non-exclusive assistance with managed-care contracts in exchange for \$3,500/year. STE SMF ¶ 19. That is the only agreement between those two parties, *id.*, and there is no evidence of any other involvement by Health in the daily operations of STOPNC. STE SMF ¶¶ 10, 19. Hospital also has a written agreement to provide certain fee-based services—accounting, food services, and instrument sterilization—to STOPNC, all of which are defined in an agreement. STE SMF ¶ 20. It is the corporate policy of Health to have written agreements for these kinds of service arrangements. STE SMF ¶ 19.

These facts are undisputed, and they are entirely insufficient to show that the Saint Thomas Entities exercised, or even had the right to exercise, actual control over the STOPNC Defendants.

STANDARD FOR GRANTING SUMMARY JUDGMENT

Summary judgment should be granted when “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a). In determining whether there is a genuine dispute, the Court “must view the evidence in the light most favorable to the opposing party.” *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (internal quotations and citation omitted). When the party having the burden of proof on the issue at trial cannot establish a necessary element of his or her claim, summary judgment against that party is appropriate. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

In such circumstances, the moving party bears the initial burden of demonstrating the absence of any genuine dispute as to a material fact of consequence and supporting that motion with “affidavits, admissions, or other materials of evidentiary quality.” *Prall v. City of Boston*, 985 F. Supp. 2d 115, 119 (D. Mass 2013) (citing *Mulvihill v. Top-Flite Golf Co.*, 335 F.3d 15, 19 (1st Cir. 2003)). “Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial,” and summary judgment should be granted in favor of the movant. *Scott v. Harris*, 550 U.S. 372, 380 (2007) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986)).

ARGUMENT AND AUTHORITIES

It is undisputed that the Saint Thomas Entities neither procured nor injected any of the Tennessee Plaintiffs with MPA compounded by NECC. The Tennessee Plaintiffs’ liability theories are therefore premised on imputing the liability of the STOPNC Defendants to the Saint Thomas Entities. This attempt fails under both their remaining vicarious liability theories—agency⁷ and their “direct liability” theory.

⁷ The Court dismissed the Tennessee Plaintiffs’ attempt to impute liability based on an alter ego for failure to state a claim. Memorandum of Decision (Docket #1360) at 50. As explained in note 4, *supra*, the Saint

I. There Is No Evidence to Support Vicarious Liability Against the Saint Thomas Entities Under an Actual Agency Theory

As noted, the Tennessee Plaintiffs allege that STOPNC and its physicians and nurses were the actual or apparent agents of one or more of the Saint Thomas Entities. Vicarious liability allows a plaintiff to hold one party liable for the acts of another based on the relationship between the actor and the third party. It applies when “liability attaches under the family purpose doctrine, *respondeat superior*, or similar circumstance where liability is vicarious due to an agency-type relationship between the active, or actual, wrongdoer and the one who is vicariously liable.” *Browder v. Morris*, 975 S.W.2d 308, 312 (Tenn. 1998) (emphasis added). Where an agency relationship exists, “the principal may be bound by the acts of the agent performed on the principal’s behalf and within the actual or apparent scope of the agency.” *Boren ex rel. Boren v. Weeks*, 251 S.W.3d 426, 432 (Tenn. 2008) (citing *White v. Revco Discount Drug Ctrs., Inc.*, 33 S.W.3d 713, 723 (Tenn. 2000)).

An agency relationship does not require an explicit agreement or contract, but depends upon the particular facts of the case. *Revco*, 33 S.W.3d at 723. “[W]hether an agency has been created is to be determined by the relation of the parties as they in fact exist under their agreement or acts.” *Id.* (quoting *McCay v. Mitchell*, 463 S.W.2d 710, 715 (Tenn. Ct. App. 1970)).

The agency inquiry takes into account both the principal’s right of control and any actual control over the agent. *Id.* The principal’s ***right to control*** the actions of the agent is “the essential test” in determining whether an agency relationship exists. *Jack Daniel Distillery v. Jackson*, 740 S.W.2d 413, 416 (Tenn. 1987). Actual control may be even more significant in the final analysis. *Revco*, 33 S.W.3d at 7123 (citing *Parker v. Vanderbilt Univ.*, 767 S.W.2d 412, 416 (Tenn. Ct. App. 1988)). The undisputed facts show that the Saint Thomas Entities did not have control over any

Thomas Entities move globally here against the actual agency claims and reserve their rights to seek summary judgment on the apparent and ostensible agency theories in representative cases.

of the STOPNC Defendants, did not attempt to exercise any such control, and under Tennessee law, were precluded from exercising any control over Dr. Culclasure. Summary judgment should therefore be granted on Plaintiffs' actual agency claims.

A. The Saint Thomas Entities Neither Had Nor Exercised Control Over the STOPNC Defendants

As explained above, it is undisputed that neither Health nor Hospital owned any interest in, or had any contractual or other right to direct or control the operations of, STOPNC. Under Tennessee law, Network's mere status as a 50% owner or member of STOPNC—a Tennessee limited liability company—does not render it liable for the acts of STOPNC in either tort or contract. *See* TENN. CODE ANN. § 48-217-101(a)(1) ([A] member . . . of an LLC does not have any personal obligation and is not otherwise personally liable for the acts, debts, liabilities, or obligations of the LLC whether such arise in contract, tort or otherwise.”).

Moreover, Network lacked practical control over STOPNC's operations and pharmaceutical procurement. It had only a 50% ownership interest and the right to appoint two members of STOPNC's four directors, STE SMF ¶¶ 5-8, so the Network-appointed board members did not have a majority vote. And, as noted, their role was in corporate governance—corporate oversight of STOPNC's financial condition—not directing STOPNC's operations. STE SMF ¶¶ 8-10. Instead, STOPNC was managed by Howell Allen Clinic pursuant to a written management agreement, and Howell Allen Clinic employees fulfilled the roles of Medical Director and Facilities Director, charged with overseeing the day-to-day operations of STOPNC and reporting directly to Howell Allen Clinic leadership. STE SMF ¶ 10. There is absolutely nothing in the record to suggest that the Saint Thomas Entities dictated policies for, much less overrode the Howell Allen Clinic in decisions affecting, the administration or management of STOPNC.

With respect to the specific claims at issue here, there is nothing in the record to show that the Saint Thomas Entities had any control over or involvement in the procurement of medicines for STOPNC. In fact, the record conclusively shows the opposite:

- STOPNC was not subject to any policies or requirements of Health or Hospital regarding medicines;⁸
- STOPNC was a 50% investment by Network in a Tennessee limited liability company, with its own board, management and staff separate and apart from any of the Saint Thomas Entities;⁹
- Neither Hospital nor Health nor Network has ever supplied medicines or pharmaceutical procurement services for STOPNC;¹⁰
- STOPNC made its own decisions about medicines and never consulted with any of the Saint Thomas Entities about purchasing from a compounding pharmacy;¹¹ and
- There is no evidence that any employee of any of the Saint Thomas Entities knew that STOPNC was purchasing from NECC prior to the outbreak.¹²

The Tennessee Plaintiffs cannot demonstrate that any of the STOPNC Defendants were authorized to act on behalf of the Saint Thomas Entities in general or in particular with respect to purchasing and dispensing pharmaceutical products. The actual agency claims should be summarily adjudicated.

B. The Saint Thomas Entities Cannot Be Vicariously Liable for any Claims Against Dr. Culclasure

The Saint Thomas Entities cannot be vicariously liable for the Tennessee Plaintiffs' healthcare liability claims against Dr. Culclasure due to Tennessee's prohibition on the corporate practice of medicine. *See* TENN. CODE ANN. § 68–11–205; *Med. Educ. Assistance Corp. v. State*

⁸ STE SMF ¶ 14.

⁹ STE SMF ¶¶ 5, 7-8.

¹⁰ STE SMF ¶ 15.

¹¹ STE SMF ¶¶ 14-15, 17-18.

¹² STE SMF ¶ 18.

ex rel. E. Tenn. State Univ. Quillen Coll. of Med., 19 S.W.3d 803, 813 (Tenn. Ct. App. 1999) (“The corporate practice of medicine is enjoined in Tennessee by T.C.A § 68–11–205.”). Dr. Culclasure was not employed by any of the Saint Thomas Entities, and all of the Saint Thomas Entities were “legally precluded from controlling the means and methods by which physicians render medical care and treatment to . . . patients.” *See Thomas ex rel. Thomas v. Oldfield*, No. M2007-01693-COA-R3-CV, 2008 WL 2278512, at *3 (Tenn. Ct. App. June 2, 2008) (citations omitted). Because the corporate practice of medicine doctrine prohibits the Saint Thomas Entities from directing healthcare decisions by Dr. Culclasure, the Saint Thomas Entities cannot be vicariously liable for his professional decisions. Thus, any healthcare liability claims against Dr. Culclasure cannot form the predicate for imposing vicarious liability against the Saint Thomas Entities and should be rendered against the Tennessee Plaintiffs.

II. The Claims for “Direct Liability” Lack Any Legally Cognizable Duty

Some of the Tennessee Plaintiffs claim the Saint Thomas Entities are directly liable to them based upon a purported failure of these Defendants to keep STOPNC from ordering medication from NECC or compounding pharmacies in general. *See, e.g.*, Berry Compl. ¶ 27(iv)(a) (alleging negligence in operating STOPNC “in a manner which facilitated the procurement of injectable steroids from NECC . . . without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds”).¹³ These claims imply that the Saint Thomas Entities owed these Plaintiffs some unspecified duty to manage STOPNC, a limited

¹³ Plaintiffs have attempted to provide additional specifics in their contention interrogatory responses, but have not amended the complaints that contain the direct-liability allegations. STE SMF ¶ 21. Even attributing significance to these contentions, they are not enough because, as demonstrated above, there is absolutely no evidence that the Saint Thomas Entities had any knowledge of or input into STOPNC’s pharmaceutical purchasing practices, and, as a matter of law, they had no duty to the Tennessee Plaintiffs in that regard.

liability company, in a way to prevent their injuries. These claims fail first because the Tennessee Plaintiffs cannot cite to any legal duty owed to them by the Saint Thomas Entities.

A. The Tennessee Limited Liability Company (“LLC”) Act Precludes Member Liability to Plaintiffs

As a Tennessee LLC organized in 1999, STOPNC is subject to the Tennessee Limited Liability Company Act, compiled in chapters 201-248 of Title 48 of the Tennessee Code. *See* TENN. CODE ANN. § 48-249-102(15). Accordingly, Network, as a member of STOPNC, is afforded the limited liability protections of the Act, and cannot be held liable for any tort committed by STOPNC (or by Howell Allen Clinic, a separate member of STOPNC), unless Network itself participated in the alleged tort. *See id.* § 48-217-101(a). Moreover, neither Network, nor the Network-appointed Governors of STOPNC (Craig Polkow and Dale Batchelor, M.D.) owed a duty of care to STOPNC’s patients.

The Tennessee LLC Act’s liability limitation provides:

(a) Limited Liability Rule.

(1) Except as provided in subsections (e) and (f), *a member*, holder of financial interest, governor, manager, employee or other agent *of an LLC does not have any personal obligation and is not otherwise personally liable for the acts, debts, liabilities, or obligations of the LLC whether such arise in contract, tort or otherwise.*

(2) *A member*, holder of financial interest, governor, manager, employee or other agent of an LLC does not have any personal obligation *and is not otherwise personally liable for the acts or omissions of any other member*, manager, governor, employee or other agent of the LLC.

(3) Notwithstanding subdivisions (a)(1) and (2), a member, holder of financial interest, governor, manager, employee or other agent may become personally liable in contract, tort or otherwise *by reason of such person’s own acts or conduct.*

TENN. CODE ANN. § 48-217-101(a) (emphasis added); *see also* TENN. CODE ANN. § 48-249-114(a)(1)–(2).

Based on this statute, Tennessee courts hold that members, governors, or directors of an LLC are not individually liable for torts committed by the LLC when there is no allegation the member had participated in or enabled the tort in question to occur. *See, e.g., Causey v. Dipak Lachmandes*, No. 3:04-0797, 2005 WL 2000625, at *5 (M.D. Tenn. Aug. 18, 2005).

“Under Tennessee law, a corporate officer is only personally liable for torts in which he or she participated in the wrong.” *Menuskin v. Williams*, 145 F.3d 755, 762 (6th Cir. 1998) (citing *Cooper v. Cordova Sand & Gravel Co.*, 485 S.W.2d 261, 271–72 (Tenn. Ct. App. 1971)). “For a director to become directly liable to a creditor, there must be some violation of a statutory duty, some other conduct that establishes a privity of contract, or a tortious injury to the creditor for which an action *ex delicto* will lie.” *Judds v. Pritchard*, No. 01A01-9701-CV-00030, 1997 WL 589070, at *3 (Tenn. Ct. App. Sept. 24, 1997) (citing *Merriman v. Smith*, 599 S.W.2d 548, 552 (Tenn. Ct. App. 1979)). “[O]fficers of a corporation are personally liable for tortious conduct of the corporation if they personally took part in the commission of the tort or specifically directed other officers, agents, or employees of the corporation to commit the tortious act.” *Word Music, LLC v. Lynns Corp. of Am.*, No. 3:09-0411, 2010 WL 3619815, at *8 (M.D. Tenn. Sept. 13, 2010), report and recommendation adopted in relevant part, 2010 WL 3951985 (quoting *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1579 (Fed. Cir. 1996)).

This is consistent with the rule in most jurisdictions:

Except where the named individual was shown to have managed or participated in the tortious act, corporate officers have in most cases been held not personally liable for injury or death attributable to a subordinate employee’s negligence in connection with corporately owned or operated land, premises, or buildings. But such liability has been imposed where, ***after having been informed of its existence***, an official of a corporation failed or neglected to take any steps to correct or remedy a dangerous condition on corporate land.

W.A. Harrington, *Personal civil liability of officer or director of corporation for negligence of subordinate corporate employee causing personal injury or death of third person*, 90 A.L.R.3d 916, § 2 (Originally published in 1979) (footnotes omitted) (emphasis added).

“Where, however, an officer or director did not personally participate in the tortious conduct, has no knowledge of it, or did not consent to it, he or she will not be held individually liable.” *In re Fresenius Granuflo/Naturalyte Dialysate Prods. Liab. Litig.*, 76 F. Supp. 3d 321, 336 (D. Mass. 2015) (applying California law) (citing *Frances T. v. Village Green Owners Ass’n*, 723 P.2d 573, 580 (Cal. 1986)). If a director (who has a fiduciary duty to the company) cannot be held liable for the tortious acts of an employee, then an owner who did nothing more than appoint the board member cannot be held liable for such acts. Here, there is no evidence that Network, much less its parent company Health or sister company Hospital, participated in Nurse Schamberg’s or Dr. Culclasure’s decision to start purchasing medication from NECC.

Other than the mere fact of its membership interest in STOPNC, Network’s only “participation” in the business of STOPNC was via its appointment of two members of STOPNC’s Board of Governors: Craig Polkow (former CFO of Saint Thomas Health) and Dale Batchelor, M.D. (former Chief Medical Officer of St. Thomas Hospital). As explained above in part I.A., the Board of Governors was not involved in the day-to-day business decisions of STOPNC (which were delegated to Howell Allen Clinic) and did not participate in any decisions either to purchase from NECC generally, nor the decision to purchase the lots of MPA from NECC that turned out to be contaminated. Accordingly, none of the Saint Thomas Entities participated in or authorized the alleged tortious conduct, and so they cannot be held directly liable to Plaintiffs.

B. There is No Direct Duty Between Plaintiffs and STOPNC’s Directors, Much Less Its Owners (or Owner’s Affiliates)

To be liable for negligence, a plaintiff must prove: “(1) a duty of care owed by defendant to plaintiff; (2) conduct by the defendant falling below the standard of care amounting to a breach

of that duty; (3) an injury; (4) causation in fact; and (5) proximate or legal cause.” *Causey*, 2005 WL 2000625, at *3 (citing *Colin v. City of Savannah*, 966 S.W.2d 34, 39 (Tenn. 1998)).

The Tennessee Plaintiffs have no evidence suggesting that any of the Saint Thomas Entities owed any duty of care to any Plaintiff while they were on the STOPNC premises, receiving medical care from STOPNC staff subject to STOPNC policies. The treatment was received from STOPNC staff, not employees of any of the Saint Thomas Entities.

As to the STOPNC Governors appointed by Network (Craig Polkow, Dale Batchelor, M.D., and Dawn Rudolph),¹⁴ Plaintiffs again have no evidence of any duty owed by them directly to Plaintiffs. Neither Governor was involved in the actual provision of medical care to any person while receiving treatment on STOPNC premises, from STOPNC staff, pursuant to STOPNC policies and procedures.¹⁵

This is because Tennessee law does not imply a duty from directors to customers, creditors, or members of the general public. Instead, absent a duty created by statute, or in the entity’s organizing documents, directors are agents of the corporation, and owe their duties to the corporation and its shareholders, and not to others. *See Jones v. First State Bank*, 13 S.W.2d 326, 327 (Tenn. 1929); *Deadrick v. Bank of Commerce*, 45 S.W. 786, 788 (1898).¹⁶ As explained below, neither Network (the 50% owner in STOPNC) nor Network-appointed board members had any duty to STOPNC patients by the terms of the STOPNC Operating Agreement or Articles of

¹⁴ STE SMF ¶ 8.

¹⁵ If any duty were owed by the Network Governors, it was to STOPNC, and to STOPNC’s members, Howell Allen Clinic and Network. Plaintiffs’ complaint against Network is arguably an attempt to bring a derivative claim against Network and the Network governors in the clothing of a direct negligence claim. Needless to say, the Tennessee Plaintiffs are not members of STOPNC, and therefore, have no standing to bring what is in substance a derivative claim on its behalf, regardless of how that claim is disguised.

¹⁶ Although this principle originated in the context of creditor and account holder suits against bank directors, *see* Richard B. Dyson, *The Director’s Liability for Negligence*, 40 Ind. L.J. 342, 343–44 (1965), it applies to all types of corporate directors under Tennessee law. *See, e.g., Merriman v. Smith*, 599 S.W.2d 548, 552, 554 (Tenn. Ct. App. 1979) (applying *Jones*, *Deadrick*, and similar cases to suit by creditors of insurance corporation against directors of the corporation).

Organization. They likewise did not voluntarily assume any such duty because they had no participation in the day-to-day operations of STOPNC. Instead, those duties were contractually delegated to Howell Allen Clinic and its staff.

C. The Terms of the STOPNC Operating Agreement Confirm Network Owed No Duty to any Plaintiff

Courts look to an LLC's operating agreements to determine if a member owes a duty to a third party, or if such duties are delegated to others. *See e.g., Spaulding v. Honeywell Int'l, Inc.*, 646 S.E.2d 645, 650–51 (N.C. Ct. App. 2007) (reviewing LLC's operating agreement to determine whether defendant member had undertaken to provide a safe working environment, and affirming summary judgment for the member because the agreement had no such undertaking). Here, the STOPNC Operating Agreement authorized the Board of Governors to delegate day-to-day operations to the others. STE SMF ¶¶ 9-10. Under the Services Agreement, the day-to-day operations of STOPNC (including procurement decisions such as where to buy medication) were delegated to the Howell Allen Clinic. *Id.* Specifically, Howell Allen Clinic was to assume the “Medical Directorship,” “Provide direction and leadership for the Medical Staff,” “Monitor quality assurance and patient care,” and “Provide all staff.” *Id.* These delegations were carried out by STOPNC management, not the Board of Governors, and were executed on behalf of STOPNC by Tina Sullivan, RN Director of STOPNC, and on behalf of Howell Allen Clinic by Mark Mason and Scott Butler. None of these individuals were employees of Network, Health or Hospital. STE SMF ¶¶ 9-10. As such, any duty to patients of STOPNC was delegated to Howell Allen Clinic, and the staff it provided to STOPNC.

D. This Court Previously Dismissed the Veil-Piercing Claims on the Pleadings

Across the country, courts routinely apply corporate veil-piercing doctrine to determine whether the members of an LLC can be liable for the actions or debts of an LLC. 2 F. HODGE O'NEAL & ROBERT B. THOMPSON, CLOSE CORP AND LLCs: LAW AND PRACTICE § 8:23 (rev. 3d

ed.) (collecting cases). Tennessee is no exception. *See, e.g., Edmunds v. Delta Partners, L.L.C.*, 403 S.W.3d 812, 828 (Tenn. Ct. App. 2012) (“The doctrine of piercing the corporate veil applies equally to cases in which a party seeks to pierce the veil of a limited liability company.”); *In re Steffner*, 479 B.R. 746, 755 (Bankr. E.D. Tenn. 2012); *cf. Rogers v. Louisville Land Co.*, 367 S.W.3d 196, 215 (Tenn. 2012) (Tennessee courts are directed to disregard a corporation’s identity “with great caution and not precipitately” (citations omitted)). Here, this Court previously dismissed Plaintiffs’ veil-piercing claims on the pleadings. *See* Memorandum of Opinion (Docket #1360) at 49-50. Accordingly, there is no basis for holding any of the Saint Thomas Entities liable to the Tennessee Plaintiffs based on their corporate relationships.

Independently, these claims fail for the same lack of proof explained above in part I. Even if the Tennessee Plaintiffs could identify some duty owed to them directly by the Saint Thomas Entities, the undisputed record described above demonstrates that the factual premise—that any of the Saint Thomas Entities were in fact operating STOPNC or had any involvement in the procurement of or policies relating to obtaining medicines—is demonstrably false. Thus, there is no evidentiary basis for such a claim, and it should be eliminated by summary judgment.

CONCLUSION AND PRAYER

For these reasons, the Saint Thomas Entities request that the Court: (i) grant summary judgment on the actual agency and direct liability claims brought by the Tennessee Plaintiffs; and (ii) grant such other and further relief to which the Saint Thomas Entities are entitled.

Dated March 15, 2016

SAINT THOMAS WEST HOSPITAL,
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CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 15th day of March, 2016.

/s/ Sarah P. Kelly
SARAH P. KELLY